Complete Summary

GUIDELINE TITLE

Chiropractic management of fibromyalgia syndrome: summary of clinical practice recommendations for the Commission of the Council on Chiropractic Guidelines and Practice Parameters.

BIBLIOGRAPHIC SOURCE(S)

Chiropractic management of fibromyalgia syndrome: summary of clinical practice recommendations from the commission of the Council on Chiropractic Guidelines and Practice Parameters. Lexington (SC): Council on Chiropractic Guidelines and Practice Parameters (CCGPP); 2009. 4 p.

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Fibromyalgia syndrome

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Chiropractic
Physical Medicine and Rehabilitation
Rheumatology

INTENDED USERS

Chiropractors
Occupational Therapists
Physical Therapists

GUIDELINE OBJECTIVE(S)

To perform a comprehensive review of the literature for the most commonly used treatment procedures in chiropractic for fibromyalgia syndrome (FMS) and to provide recommendations for management of FMS using conservative and nonpharmaceutical therapies

TARGET POPULATION

Patients with fibromyalgia syndrome

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Pressure algometry
2. Fibromyalgia Impact Questionnaire (FIQ)

Management/Treatment

1. Aerobic exercise, muscle strength training, movement and body awareness
2. Cognitive behavioral therapy (CBT)
3. Manual therapies such as massage and manipulation
4. Vitamins, herbs, and diet modification
5. Medications such as amitriptyline andÂ cyclobenzaprine used alone, or in combination with selective serotonin reuptake inhibitors (SSRIs) or serotonin-norepinephrine reuptake inhibitors (SNRIs)
6. Balneotherapy (spa therapy)
7. Acupuncture

MAJOR OUTCOMES CONSIDERED

Fibromyalgia symptoms

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Search Strategy

The search strategy for this literature review was focused on conservative nonpharmaceutical treatments for fibromyalgia (FMS), including chiropractic manipulative therapy. Therefore,Â the search included any conservative therapy that might be included within the scope of chiropractic practice, in addition to spinal manipulation. Articles that were opinion pieces, hypotheses, extrapolations from basic science research, and other nonobservational types of articles were excluded fromÂ the review.

AÂ systematic approach was used to reviewing the FMS literature by following this sequence of online searching strategies:

- A search of the Cochrane Database of Systematic Reviews for systematic reviews and meta-analyses of randomized controlled clinical trials (RCTs) for FMS.
- A search of the National Guideline Clearinghouse (NGC) for any published guidelines for the management of FMS.
- Direct searches of several online databases for additional RCTs that might not have been included in previous systematic reviews or meta-analyses. These direct searches included the following databases: PubMed, Cochrane Central Register of Controlled Trials, Allied and Complementary Medicine (AMED), Medline, and Cumulative Index to Nursing and Allied Health Literature (CINAHL).
- Additional searching of the Manual, Alternative, and Natural Therapy Index System (MANTIS) and Index to Chiropractic Literature (ICL) for any additional literature on FMS, including experimental and observational studies such as case reports and case series.

The keywords used in our search strategy included the terms fibromyalgia, fibrositis, and fibromyalgia syndrome and covered the literature published in the English language between 1966 and 2006. We did not restrict the searches by using the term chiropractic, with the exception of one of the searches within the specific confines of the MANTIS and ICL databases. The titles of all retrieved studies were reviewed for their relevance to chiropractic practice and scope, and the abstracts of any potentially relevant studies were further reviewed before obtaining full text copies of the entire article. Studies that involved injection, medication, surgery, or other invasive therapies were excluded fromÂ the review. Two systematic reviews of the antidepressant medication literature were included because this class of medication is considered an integral component of the standard medical management of FMS syndrome, albeit outside the scope of chiropractic practice.

A manual review of the reference lists of the previously noted Cochrane systematic reviews and meta-analyses and the NGC practice guidelines found that the most recent of these publications had searched the FMS literature through the

year 2002.Â Evidence review groupÂ (ERG) therefore performedÂ their own searches for additional controlled trials using the keywords fibromyalgia and fibromyalgia syndrome between the years January 2000 and June 2006 on the following databases: MEDLINE, CINAHL, AMED, Cochrane Central Register of Controlled Trials, and PubMed. The rationale for going back to the year 2000 was to confirm that we did not miss any relevant studies and to provide some overlap for comparison with the references contained in the search strategies of the previously reported FMS systematic reviews, meta-analyses, and practice guidelines.Â The intent was to attempt to find any additional clinical trials that were not included in the reviews performed by the previous meta-analyses and systematic reviews by cross-referencing the ERG group'sÂ list against the list of references from the prior studies.

In addition to searching these standard online databases for randomized controlled trials,Â the ERG groupÂ specifically wanted to capture any type of chiropractic literature, including observational studies, that might have been published in nonindexed journals. Therefore,Â they specifically performed another comprehensive search of the MANTIS and ICL databases, which are more inclusive of the chiropractic and complementary and alternative medical (CAM) therapy literature.Â Two search strategies were used on these databases. First,Â a wide search using the terms fibromyalgia and fibromyalgia syndrome was performed without any restrictions to journal type, but restricted the year of publication from 1990 to 2006, The rationale for this search strategy was simple: 1990 is generally considered the inaugural year for fibromyalgia becoming officially recognized as a diagnosis by virtue of publication of the American College of Rheumatology (ACR) criteria for diagnosis of FMS.Â The second search strategy was to use the keywords fibromyalgia AND chiropractic for the years of publication from 1950 to 2006.Â The ERG group also used reference tracking to ensure that the search was comprehensive.

NUMBER OF SOURCE DOCUMENTS

- Initial search: 8 systematic reviews, 3 meta-analyses, 5 practice guidelines, and 44 randomized controlled trials (RCTs)Â were included.
- Additional studies from Manual, Alternative, and Natural Therapy Index System (MANTIS) and Index to Chiropractic Literature (ICL) searches: 17 RCTs, 2 surveys, 2 case-control studies, 14 case series, and 3 case reports were included.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

A. **The Oxford Rating Scale**

1a: Systematic review with homogeneity of randomized controlled trials (RCTs)

1b: Individual RCT with narrow confidence interval

2a: Systematic review with homogeneity of cohort studies

2b: Individual cohort study or low-quality RCT

3a: Systematic review with homogeneity of case-control studies

3b: Individual case-control study

4: Case series, low-quality cohort or case-control studies

5: Expert opinion

B. **The Scottish Intercollegiate Guidelines Network (SIGN) Checklist**
   1. ++ = All or most methodological criteria have been fulfilled/bias has been maximally reduced.
   2. + = Some of the criteria have been fulfilled/bias has been somewhat reduced.
   3. - = Few or no criteria fulfilled/bias is clearly present.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Evaluation and Rating Systems

As relevant studies for this guideline were identified,Â full text versions of the articles were obtained and reviewed using several recognized protocols. The systematic reviews, meta-analyses, and randomized trials were reviewed using the Oxford Rating Scale developed by the Centre for Evidence-Based Medicine (http://www.library.utoronto.ca/medicine/ebm) and the appropriate evidence rating checklists developed by the Scottish Intercollegiate Guidelines Network (SIGN) (http://www.sign.ac.uk/methodology/index.html) (see the "Rating Scheme for the Strength of Evidence" field). There are separate SIGN checklists for each type of experimental and higher-quality observational studies. The guidelines retrieved from the National Guideline Clearinghouse (NGC) were evaluated using the appraisal instrument/checklist developed by the Appraisal of Guidelines for Research and Evaluation (AGREE) Collaboration (www.agreecollaboration.org).

Finally, after summarizing the literature into evidence tables,Â some evidence rating tables were developed based uponÂ the interpretation and evaluation of the quality of this literature. The evidence rating tables followed a standard format suggested by the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) (http://www.ccgpp.org) as outlined in theÂ "Rating Scheme for the Strength of the Recommendation" field.

UseÂ of Evidence Tables

Evidence tables for RCTs rated by the team were constructed using categorical information shown reliable in other studies. Templates were provided to each team member for recording this information during the course of their review.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)
Expert Consensus (Nominal Group Technique)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Team Selection and Orientation Training of Team Leaders

The Council on Chiropractic Guidelines and Practice Parameters (CCGPP) appointed 2 cochairs for the commission, each having experience in practice, structured literature review, and formal consensus processes, either having been involved with one or more of original clinical and educational research, the Agency for Health Care Policy and Research acute low back pain guidelines, the RAND corporation task forces on appropriateness for use of spinal manipulation, and earlier CCGPP Mercy Center chiropractic guidelines. Team leaders were nominated by the commission cochairs and recommended to the council for approval. Selection was based upon identification of individuals with clinical experience, additional crosstraining in the content area of their assigned domain, and/or scholarly work. Team members were selected from a multidisciplinary list of practitioners and content experts that had been solicited from the council stakeholders and colleges. Additional nominees were identified to serve as consultants based on content expertise.

A team leader packet of information, derived from the literature, sets out motivation and methodology, including standardized instruments, with example formats serving as suggestion for the final report. An orientation meeting was convened with all team leaders and available consultants at the 2004 Association of Chiropractic Colleges and Research Agenda Conference held in Las Vegas, Nevada. Survey of the literature, rating, and interpretation of evidence commenced in July of 2004.

Summary of the Process

Balancing patient-centered and evidence-based values imparts similar internal tensions with tendency for the best intent of individuals to succumb to training biases and personal preferences. Four strategies were used to minimize this problem while empowering legitimate and informed interpretation of the literature:

1. Review of the literature by a panel of experts including those who do use and those who do not use the methods under review.
2. Standardized and validated structured instruments for rating the quality of and results from the literature.

3. Formal consensus process, based on Delphi and Nominal Group Process methods, to adjudicate differences in professional opinion on the literature or to address important areas where literature is weak or lacking.
4. Wide stakeholder review with opportunity for critical comment offered to all stakeholder groups
   including patients, professionals, policymakers, and third-party payers.

Process development was guided by experience of commission members with the RAND consensus process, Cochrane collaboration, Agency for Health Care Policy and Research, and published recommendations modified to the needs of the council.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Council on Chiropractic Guidelines and Practice Parameters (CCGPP) Protocol for Grading of Recommendations

Grade A: good evidence from relevant studies

- Studies based on appropriate research designs of sufficient strength to answer the questions addressed
- Results are both clinically important and consistent with minor exceptions at most
- Results are free of any significant doubts about generalizability, bias, and flaws in research design
- Studies with negative results have sufficiently large sample sizes to have adequate statistical power

Grade B: fair evidence from relevant studies

- Studies based on appropriate research designs of sufficient strength, but with some uncertainty due to inconsistencies in results, or minor doubts about generalizability, bias, design flaws, or sample size
- Results from weaker designs, but confirmed in separate studies

Grade C: limited evidence

- Studies of appropriate design, but substantial uncertainty due to inconsistencies in results or due to serious doubts about generalizability, bias, research design flaws, or adequacy of sample size
- Results from a limited number of studies or because of weak design for answering the question addressed

Grade D: expert opinion, and usual and customary practice

- Evidence from expert opinion only; research cannot be or has not been done.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Stakeholder Review and Implementation

Stakeholder review of best practices is a critical step to facilitate final recommendations and implementation. This process affords the opportunity for individuals and groups that can be impacted by best practices to provide comment and documentation for consideration by the team.

Two strategies were used to reach stakeholders for review and comment on the document itself. On completion of the draft document of best practices, a summary of the best practices document was posted on a widely accessed health care Web site (spine-health.com) that experienced a public hit rate of 2.5 to 3.0 million per month during 2005. Separately, on the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) Web site, the document was posted and notification made to colleges, state and national associations, and third-party payers.

Interactive electronic questionnaires, developed by the Dissemination, Implementation, Evaluation, and Review (DIER) committee of CCGPP,Â were available for stakeholder comments online. Those choosing to commentÂ were invited to submit documentation for their opinions directly to CCGPP. The postings will be maintained for 60 days and comments harvested electronically and provided to the cochair of the commission. The cochair will group similar comments and develop summary questions that will be posted, with the original comments and any supportive documentation, to the team for review and response. A tally of comments by group along with the questions and responses from the team will be made a part of the Appendix in the final document release.

The final document will include any changes in conclusions of the team made in response to stakeholder input.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Strength ofÂ recommendationÂ ratings (A-D) are provided at the end of "Major Recommendations" field.

Summary of Clinical Practice Recommendations

Topic	Conclusions and Strength of Evidence Rating
Fibromyalgia Syndrome (FMS)	

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Fibromyalgia Syndrome (FMS)	
Evaluation	**RATING A: Pressure Algometry** There is strong evidence that pressure algometry has high reliability and validity in the assessment of the Tender Points (TePs) found in fibromyalgia syndrome. **RATING A: Fibromyalgia Impact Questionnaire (FIQ)** The FIQ has achieved wide recognition as a reliable and valid instrument as part of FMS management and research, and has been translated into several languages.
Manual Therapies	**RATING B: Massage** There is moderate evidence from several randomized controlled trials (RCTs) and one systematic review that massage is helpful in improving sleep and reducing anxiety in chronic pain. **RATING C: Manipulation** There is limited evidence consisting of one small chiropractic pilot RCT that manipulation may relieve pain in FMS. The literature also contains two chiropractic and two osteopathic manipulation case reports/series.
Exercise	**RATING A: Aerobic exercise** There is strong evidence from multiple RCTs/systematic reviews that mild aerobic exercise is helpful in relieving the pain and fatigue associated with FMS. **RATING B: Muscle strength training** There is moderate evidence that mild strength training programs are helpful in FMS, however the evidence does not support moderate or heavy intensity strength training for FMS patients. **RATING C: Movement and body awareness** There is preliminary evidence from three small RCTs that gentle body awareness exercise methods such as T'ai chi and Qi Gong are helpful with FMS.
Vitamins, herbs, diet modification	**RATING C: Vitamins, herbs, diet modification** There are several small RCTs with preliminary evidence

Topic	Conclusions and Strength of Evidence Rating
Fibromyalgia Syndrome (FMS)	
	showing a potential beneficial effect of these therapies for FMS.
Cognitive Behavioral Therapy	**RATING A: Cognitive Behavioral Therapy (CBT)** There are several large RCTs and systematic reviews showing a strong treatment effect of CBT alone, and in combination with exercise and various medications, for the clinical management of FMS symptoms.
Medications*	**RATING A: Medications** The medications with the strongest evidence of effectiveness (multiple systematic reviews and RCTs) for FMS are amitriptyline and cyclobenzaprine used alone, or in combination with selective serotonin reuptake inhibitors (SSRIs) or serotonin-norepinephrine reuptake inhibitors (SNRIs). Emerging evidence is for pregabalin, gabapentin, and tramadol. No evidence for non-steroidal antiinflammatory drugs (NSAIDs) or corticosteroids used alone.
Balneotherapy (Spa therapy)	**RATING B: Balneotherapy** There is moderate evidence from several consistent RCTs showing reduction of FMS symptoms with hot water/spa treatments.
Acupuncture*	**RATING B: Acupuncture** There is one systematic review and one additional RCT that show moderate reduction of pain in FMS patients with acupuncture treatment.

*__Note__: Although prescription medications and acupuncture are outside the scope of chiropractic practice in many jurisdictions,Â they have beenÂ includedÂ in the evidence tables due to their popular and widespread usage among FMS patients.

Definitions:

Council on Chiropractic Guidelines and Practice Parameters (CCGPP) Protocol for Grading of Recommendations

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- Studies based on appropriate research designs of sufficient strength to answer the questions addressed
- Results are both clinically important and consistent with minor exceptions at most
- Results are free of any significant doubts about generalizability, bias, and flaws in research design

- Studies with negative results have sufficiently large sample sizes to have adequate statistical power

Grade B: fair evidence from relevant studies

- Studies based on appropriate research designs of sufficient strength, but with some uncertainty due to inconsistencies in results, or minor doubts about generalizability, bias, design flaws, or sample size
- Results from weaker designs, but confirmed in separate studies

Grade C: limited evidence

- Studies of appropriate design, but substantial uncertainty due to inconsistencies in results or due to serious doubts about generalizability, bias, research design flaws, or adequacy of sample size
- Results from a limited number of studies or because of weak design for answering the question addressed

Grade D: expert opinion, and usual and customary practice

- Evidence from expert opinion only; research cannot be or has not been done.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of fibromyalgia syndrome (FMS)

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

While the recommendations in this document are reflective of the current best available evidenceÂ regarding chiropractic intervention for the conditions cited,

they are not indicative of the full scope of chiropractic care in these areas. Additional research is recommended to improve the base of evidence for which anecdotal evidence indicates chiropractic intervention may be appropriate.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Chiropractic management of fibromyalgia syndrome: summary of clinical practice recommendations from the commission of the Council on Chiropractic Guidelines and Practice Parameters. Lexington (SC): Council on Chiropractic Guidelines and Practice Parameters (CCGPP); 2009. 4 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2009 Jan

GUIDELINE DEVELOPER(S)

Council on Chiropractic Guidelines & Practice Parameters - Professional Association

SOURCE(S) OF FUNDING

Council on Chiropractic Guidelines & Practice Parameters

GUIDELINE COMMITTEE

Scientific Commission of the Council on Chiropractic Guidelines and Practice Parameters

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All commission members' service was uncompensated.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) Web site.

Print copies: Submit requests to the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) Web site: www.ccgpp.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Chiropractic management of fibromyalgia syndrome: a systematic review of the literature. 2009 Jan. 16 p. Electronic copies: Available in Portable Document Format (PDF) from the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) Web site.

Print copies: Submit requests to the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) Web site:Â www.ccgpp.orgÂ orÂ *Journal of Manipulative and Physiological Therapeutics (JMPT)* at www.jmptonline.org.

The following are also available:

- Literature syntheses for the Council on Chiropractic Guidelines and Practice Parameters: methodology. 2008 Nov-Dec. 6 p. Electronic copies: Available in Portable Document Format (PDF) from the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) Web site.

- What constitutes evidence for best practice? 2008 Nov-Dec. 7 p. Electronic copies: Available in Portable Document Format (PDF) from the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on February 3, 2010. The information was verified by the guideline developer on February 19, 2010.

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